



SABM[®]
SOCIETY FOR THE ADVANCEMENT
OF PATIENT BLOOD MANAGEMENT

5TH EDITION

**SABM
ADMINISTRATIVE
AND CLINICAL
STANDARDS**

FOR PATIENT BLOOD
MANAGEMENT PROGRAMS[®]

TABLE OF CONTENTS

FOREWORD	1
STANDARD 1: LEADERSHIP AND PROGRAM STRUCTURE	4
STANDARD 2: CONSENT PROCESS AND PATIENT DIRECTIVES	7
STANDARD 3: PHYSIOLOGIC TOLERANCE OF ANEMIA	10
STANDARD 4: REVIEW AND EVALUATION OF THE PATIENT BLOOD MANAGEMENT PROGRAM	13
STANDARD 5: TRANSFUSION GUIDELINES AND PEER REVIEW OF TRANSFUSIONS	16
STANDARD 6: PREOPERATIVE ANEMIA EVALUATION AND READINESS FOR SURGERY	19
STANDARD 7: PERIOPERATIVE AUTOLOGOUS BLOOD COLLECTION FOR ADMINISTRATION	22
STANDARD 8: PHLEBOTOMY BLOOD LOSS	25
STANDARD 9: MINIMIZING BLOOD LOSS ASSOCIATED WITH SURGERY, PROCEDURES, COAGULOPATHY OR ANTIPLATELET/ ANTITHROMBOTIC MEDICATIONS	27
STANDARD 10: MASSIVE HEMORRHAGE PROTOCOL	30
STANDARD 11: MANAGEMENT OF ANEMIA IN HOSPITALIZED PATIENTS	33
STANDARD 12: MANAGING ANEMIA IN NON-SURGICAL OUTPATIENTS	35
STANDARD 13: PATIENT BLOOD MANAGEMENT FOR PEDIATRIC PATIENTS	37
STANDARDS 1-12 REFERENCES	43
STANDARD 13 REFERENCES	54
ACKNOWLEDGEMENT	57
APPENDIX	58

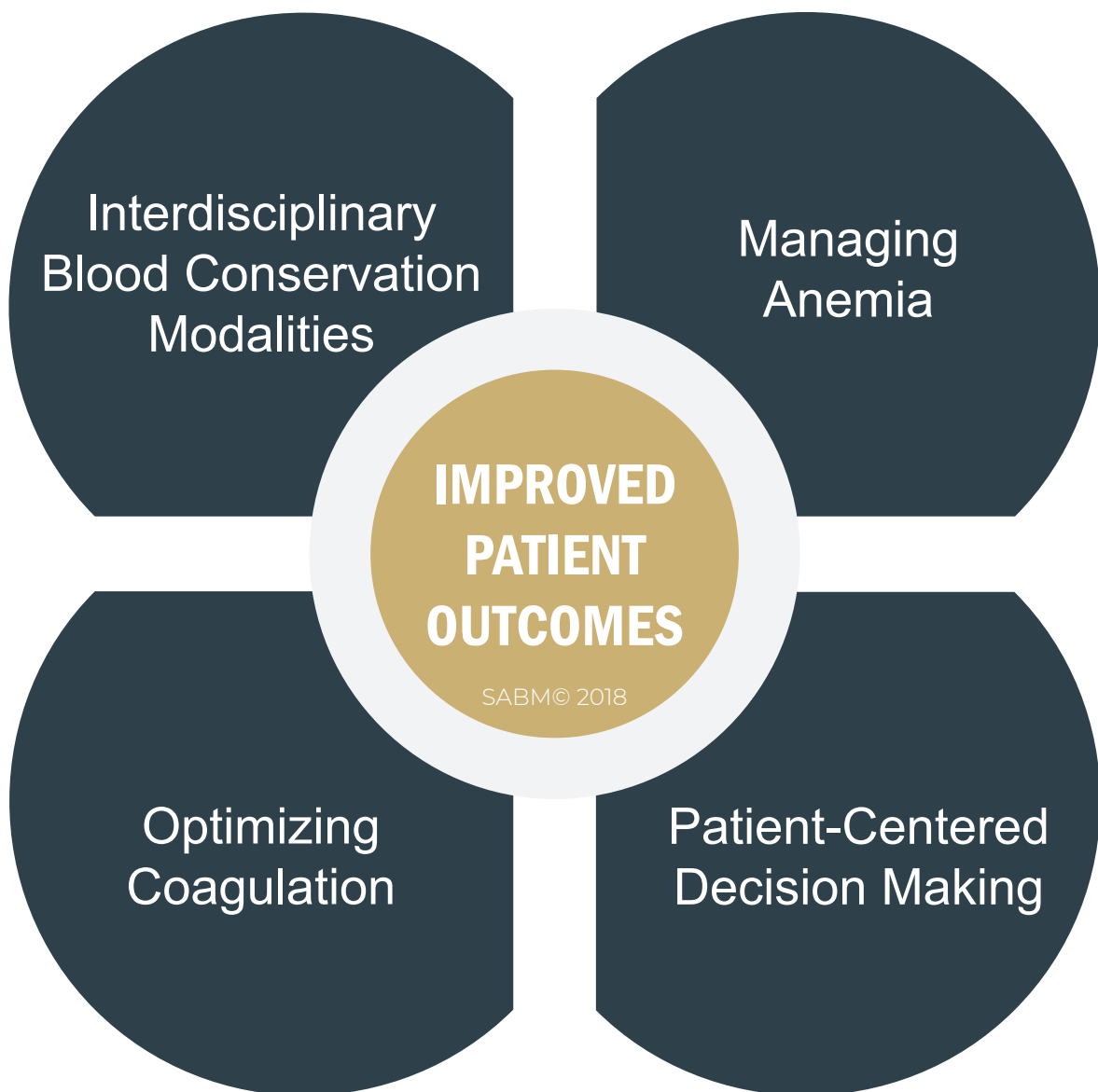
FOREWORD

Transfusion of allogeneic blood and its components has long been an integral part of healthcare delivery throughout the world. Many evidence-based criteria for clinically appropriate transfusion have been published as well as consensus guidelines based on expert opinion, yet practitioners continue to transfuse patients outside these recommended criteria and guidelines without sufficient demonstration of benefit to the recipient. As awareness of the risks associated with blood transfusion increases (including but not limited to pathogen transmission, bacterial contamination, acute lung injury, volume overload, transfusion related immunomodulation and allergic reactions) and data emerge that support restrictive transfusion practices, a shift to a lower transfusion threshold and a lower transfusion target continues in the published medical literature. This is not always reflected in daily practice and data suggest continued variation in practice and continued administration of clinically inappropriate transfusions. A growing number of publications strongly suggest that blood transfusions are not only associated with significant risk but may not provide the desired therapeutic outcome for which the transfusion was prescribed. Further, many transfusions that are medically appropriate might have been avoided if management of the patient across the full spectrum of care – inpatient and outpatient– had included efforts to reduce bleeding and blood loss and efforts to better manage anemia by therapeutic options other than transfusion. This requires that hospitals and health systems develop a program and infrastructure that facilitates a change in clinical practice to eliminate inappropriate and avoidable transfusions.

Which patients are transfused and when are they transfused? The answer often depends more on the ordering physician and the location and culture of the healthcare institution than the clinical condition of the patient. Though some patients, such as those with hemoglobinopathy or myelodysplasia, are transfusion dependent, many non-hemorrhaging patients are transfused because of a failure to diagnose, treat, and correct anemia. Commonly, plasma transfusion is used for warfarin reversal when timely use of vitamin K would have avoided the need for transfusion or factor concentrates. Such neglected opportunities are responsible for a significant number of avoidable transfusions.

The question of when blood should be transfused, that is when benefit clearly outweighs the risk, is difficult to answer. As a guiding principle, the clinician should use every opportunity to treat the patient with other effective modalities, often long before transfusion is considered. The Institute of Medicine (IOM), in its study of health care in the United States, demonstrated the great variability in transfusion practices and the frequency of transfusion. The consistent presence of wide variation in transfusion suggests an opportunity to improve care and patient outcomes by effective implementation of patient blood management.

The Society for the Advancement of Blood Management® (SABM®) is a not-for-profit professional organization that educates caregivers on the clinical issues associated with blood transfusion and their impact on patient outcomes. This is achieved through an understanding of Patient Blood Management (PBM), defined by SABM as the timely application of evidence based medical and surgical concepts designed to maintain hemoglobin concentration, optimize hemostasis and minimize blood loss to improve patient outcome. Distinct from management of the blood supply, PBM is trans-disciplinary and multi-modal clinical Management of the patient by the proactive application of four guiding principles:



Identifying an unmet medical need, SABM has developed this document, SABM Administrative and Clinical Standards for Patient Blood Management Programs®, now in its fifth edition. The SABM Standards address clinical activities related to patient blood management and are intended to optimize clinical outcomes and improve patient safety. These Standards are not intended to provide strict indications, contraindications or other criteria for the practice of clinical medicine and surgery. Clinical decisions are the sole responsibility of the health care provider and may vary from patient to patient subject to individual health care practitioner clinical judgment. As such, the SABM Standards should not be used as the only basis for making case-specific decisions regarding patient recommendations or diagnostic testing.

This document, by necessity, is evolving rather than static, since new information is rapidly emerging. Those practitioners and institutions that wish to establish a formal organization-wide patient blood management program should follow the SABM Standards. These Standards can be used to accelerate adoption of evidence-based practices and clinical guidelines in any institution, bringing proven treatment and management strategies that improve patient outcomes at the bedside.

STANDARD 1: LEADERSHIP AND PROGRAM STRUCTURE

The structure of an effective program should revolve around quality and patient safety. The purpose of the committee will be to approve policies, procedures and protocols identified as Patient Blood Management (PBM) modalities, strategies, techniques and guidelines that are evidence-based, and patient focused with an effort to avoid blood transfusions and appropriately treat anemia. The program has a clinical leadership model or structure defined by physician(s) as medical director(s) to provide clinical leadership and oversight including a project manager to provide operational leadership. The program has a defined mission, vision, values, and educational programs for health care providers, as well as a process for review of patient outcomes.

GUIDANCE

See APPENDIX: Figure 1 and Figure 2

Standard #1 defines the program. The PBM Program is supported by a defined management structure. The program is appropriately positioned within the organizational structure to

Physician leadership required in establishing clinical protocols

Program structure established through written policies and procedures

Patient outcomes are monitored

reflect strong administrative support of the program. Clinical leadership requires physicians who have knowledge and experience in the use of blood, blood components and other treatment modalities. The **designated** physicians provide leadership in establishing clinical protocols for patient blood management with an emphasis on reducing bleeding and blood loss and managing anemia. In addition, the physician medical director(s) consult with, assist, educate, hospital providers on transfusion practice and monitor blood use. The

program manager/project manager (hospital option) may be someone with training as a nurse, pharmacist, medical technologist or other individual with prior knowledge and experience in transfusion medicine or patient blood management.

Some hospitals have identified a priority to secure long term PBM culture and stability by utilizing a different structure during initial implementation. (See below graphic #___) This is accomplished by utilizing the PBM Master Committee as the alternative “staff member”. This committee was previously proposed in historic structure models as the ‘Transfusion Committee/Blood Utilization Committee’. The work that was done by this committee continues to be essential and regulatory focused, but now would shift to a position of being one of several pillars of the overarching PBM Master Committee.

An educational program, designed to provide knowledge of how the PBM works, is necessary for each staff person to understand their individual role, where to obtain support as necessary, and how to use the tools provided. In addition, provider education on the risks and benefits of blood transfusion and other treatment modalities will help facilitate and maintain a change in clinical practice and a reduction in transfusions. This change will be further facilitated by establishing metrics to monitor the impact of various patient blood management strategies.

The program must monitor patient outcomes as well as use of resources including blood products, other treatment modalities such as surgical and anesthetic techniques to reduce blood loss, techniques for minimizing procedural blood loss, perioperative blood recovery and reinfusion, normovolemic hemodilution, erythropoietic stimulating agents, intravenous iron, folic acid and other modalities for treating anemia, and other pharmacologic agents such as antifibrinolytics, factor concentrates, and topical haemostatic agents. Examples of patient outcomes include length of stay, incidence of new-onset renal failure and incidence of hospital acquired infections.

INDICATORS

- 1.1 There is a PBM written mission/, vision, values statement describing the purpose of the program and how it fits the institution’s mission and values.
- 1.2 The published evidence strongly supports all service lines adopt Patient Blood Management as standard of care. If a hospital chooses only partial adoption, a scope of service statement defines the clinical areas affected by the program.
- 1.3 PBM leadership roles are defined and adopted by the committee and executive leadership representatives.
- 1.4 Because the evidence supports implementing PBM as a standard of care hospital wide, policies/procedures/pathways/and process all support PBM recommendations with the only exception being the patient refusing any transfusion of blood product due to personal reasons.
- 1.5 Clinical policies/procedures/pathways/and process mentioned above in 1.4, should be sent through the appropriate sources of the PBM Master committee for review. This includes into hospital based EMR systems.

- 1.6 There is a comprehensive education program targeting physicians, mid-level providers, nurses, pharmacists and other ancillary health care staff regarding the patient blood management program's goals, structure, and scope. Educational activities occur at least annually.
- 1.7 There is education of new clinical personnel regarding the patient blood management program's goals, structure, and scope as part of the hospital's orientation program for newly hired personnel.
- 1.8 Quality, patient safety and performance improvement metrics are identified and defined by the PBM Clinical leadership representatives, with data collection that is reported to the hospital quality department on a scheduled basis.
- 1.9 Hospital Executive/administrative leadership is represented on the Patient Blood Management Committee.

STANDARD 2: CONSENT PROCESS AND PATIENT DIRECTIVES

There is a well-defined and consistent process for obtaining informed consent for transfusion from patients who accept transfusions. Additionally, there is a process in place for obtaining an advance directive from patients who decline transfusion for religious or other reasons. The hospital and its staff respect and support patients who decline blood and blood components.

GUIDANCE

Informed consent for transfusion is required by The Joint Commission as well as other regulatory bodies. While the essential components of consent (risks, benefits, and alternatives to allogeneic transfusion) are required by The Joint Commission and other regulatory and accrediting bodies, in many institutions the informed consent process is ill-defined and subject to significant variability across physician providers. In many hospitals, the patient's signature on an informed consent form is obtained before transfusion. This does not ensure that the patient was informed of the true risk and potential benefits of transfusion or the alternatives that are available in a hospital with a comprehensive patient blood management program. A patient's autonomy is protected by law. Patients who have a personal or religious objection to receiving blood transfusions must have documentation in the medical record of their objection to transfusion prior to initiating treatment, unless that information is unknown due to a life-threatening emergency.

The emphasis in informed consent should be on delivering an essential core content of information, in a consistent and standardized fashion, tailored to the patient's ability to understand the information. Obtaining the patient's signature is often the focus of informed consent in many hospitals, but it does not constitute informed consent in and of itself. It is merely a way of documenting that an

Informed consent is vital, should be standardized and consistently delivered

Patient autonomy a legally protected right

Advance Directives communicate wishes of patients declining transfusion

informed consent process has occurred. Many hospitals use written materials or video to ensure patient receipt of a standardized content and provide help to nurses and physicians in explaining transfusion risks, benefits, and alternatives to patients. Patients must have adequate time to ask questions and must be given the opportunity to refuse transfusion.

For patients refusing transfusion for religious, cultural or personal reasons, an advance directive that documents their refusal of blood transfusion is indicated. This directive must make clear which transfusion alternatives are acceptable to the patient and the implications of adverse outcomes (e.g. possible organ injury or death) related to refusal of blood as a life-saving intervention. The directive may only be revoked personally by the patient but may be revoked at any time.

INDICATORS

- 2.1 A hospital-wide policy requires written informed consent for transfusion that documents a discussion about the risks, benefits and competing clinical strategies or alternatives to transfusion.
- 2.2 A hospital-wide policy supports and respects the right of competent adult patients to decline blood transfusion. The policy addresses the rights of patients who are minors.
- 2.3 The hospital has a document readily available for competent adult patients to sign that functions as a directive establishing the decision to decline transfusion.
- 2.4 The document declining transfusion clearly delineates which competing clinical strategies or alternatives to allogeneic transfusion are acceptable to the patient. Alternatives include, but are not limited to, autologous transfusion modalities, human derived growth factors, essential cofactors (e.g. iron, B12, and folic acid) for red cell production, recombinant products, factor concentrates, and blood derivatives and fractions.
- 2.5 All patients have access to information regarding the risks and benefits of blood transfusion as well as the risks and benefits of refusing a transfusion. The information includes those competing clinical strategies or alternatives to blood transfusion that are available and applicable to that patient.
- 2.6 Processes allow clinical staff involved in the care of patients to quickly and easily identify competent adult patients who have declined blood transfusions.
- 2.7 For those competent adult patients entering the hospital with a previously executed blood refusal advance directive, confirmation of that patient's continued desire to refuse transfusion is obtained and documented. If the competent adult patient is unconscious or incapacitated, the advance directive is honored.

- 2.8 Education on competing clinical strategies or alternatives to and strategies to avoid blood transfusions is provided to medical staff and other health care providers. This includes but is not limited to strategies to optimize the patient's own red cell volume, minimize blood loss and harness the patient's ability to physiologically adapt to blood loss and anemia through optimization of hemodynamics and oxygenation.
- 2.9 Education on religious proscriptions against blood transfusion is available to all providers.

STANDARD 3: PHYSIOLOGIC TOLERANCE OF ANEMIA

Required equipment and guidance, through clear policies and protocols for both medical and surgical patients, are provided to optimize tissue oxygen delivery, avoid organ hypoxia and therein a reduce ischemic complications.

GUIDANCE

Policies/interventions that optimize oxygen delivery, avoid compromising critical oxygen delivery and therein ischemic complications, must recognize the complexity of individual physiology and comorbidities, as well how anemia, hemodynamics, vascular biology and oxygen delivery are related. Tissue oxygen delivery is not solely a function of hemoglobin concentration, but rather a complex interaction of hemodynamics, microcirculation, pulmonary/ artificial oxygenation and dynamic local blood flow (arteriolar and capillary) regulation. Some of these we can measure at a macro-physiologic level (cardiac output, blood pressure, vascular filling pressures, for example) and others- capillary flow, capillary density, red cell transit time, we cannot. The physiologic tolerance/intolerance of anemia cannot be directly tied to any one academic society's recommended threshold or "trigger" for transfusion. Medicine does not currently possess a "tissue critical oxygen delivery monitor". Therefore, the guidance in terms of tolerance of anemia is nuanced, subtle, and must be the judgement of skilled medical care teams, tailoring to each patient, support for hemodynamics, blood pressure, and tissue flow with a focus to reduce the pressures for transfusion and therefore to improve clinical outcomes.

The limits of critical oxygen delivery (a strict definition of shock, shift of aerobic to anaerobic glycolysis) in human anemia are between 3-5 gm/dl of Hgb in healthy individuals with intact cardiovascular reflex capabilities. Skilled management of hemodynamics and oxygenation can be used to avoid transfusion with the same or improved clinical outcomes in most otherwise healthy patients with a hemoglobin greater than 3-5 g/dl and intact cardiovascular reflex capabilities.

Rarely, patients have survived at levels of 0.2-0.6 gm/dl-Hgb, but in patients with cardiac instability, who refuse blood below 7gm/dl, the risk of mortality rises 10% for every 1 gm/dl of decreased Hgb. However, with comprehensive management of hemodynamics and critical oxygen utilization, in concert with the manipulation of complex physiology, even in severe anemia survival is possible, and the need for transfusions reduced even if they cannot be completely avoided.

Goal-directed, individualized hemodynamic and oxygenation therapy based upon a combination of functional, volumetric and oxygenation parameters, reduces the pressure on physicians for red cell transfusion as a therapeutic option, thereby improving clinical outcomes. Transfusion triggers are NOT individualized goal directed therapy. Rather an

acceptable hemoglobin range should be determined for each patient that avoids organ hypoxia.

Optimization of hemodynamics and oxygenation to maximize physiologic tolerance of anemia, should begin at the time of first physician contact (pre-admission in anemia treatment planning) and continue across the total continuum of care, particularly in the pre-operative clinic, operating room, the post-anesthesia care unit, critical care unit, the routine wards and extend into primary care follow up. Goal-directed guided therapy might utilize parameters such as stroke volume variation, individually optimized global end-diastolic volume index, cardiac index, echocardiographic analysis of cardiac function/filling, afterload and pre-load, mean arterial pressure, mixed venous oxygen, cerebral oxygenation, systemic oxygen utilization (uptake) metabolic acid production (base excess/deficit), to optimize clinical care of patients with anemia and or blood loss. Future utilization of non-invasive measures of hemodynamic cardiovascular parameters coupled with non-invasive Hgb, and tissue oxygen delivery measures are promising but not proven to the point wherein guidance can be given on parameters for utilization.

(Note: Standard 3 does not address all aspects of Physiologic Tolerance of Anemia in pediatric patients. For specific recommendations in neonates, infants, children and adolescents, please refer to Standard 13.)

INDICATORS

- 3.1 When possible and appropriate, treatment algorithms that optimize hemodynamics and perfusion are developed and adopted.
- 3.2 Treatment of hemodynamics, vaso-reactivity and delivery of oxygen to tissues take all parameters into account, not simply use a transfusion trigger.
- 3.3 There are indicators in place for determining stroke volume variability or equivalent, to assess patient's volume in order to maintain euvolemia.
- 3.4 A hemoglobin concentration alone is not the sole reason for triggering an allogeneic transfusion.
- 3.5 Efforts to avoid critical oxygen hemoglobin concentration begin at first contact or as early as possible in-patient care.
- 3.6 All patient blood management efforts are focused on avoiding critical oxygen delivery via preemptive collaborative care.
- 3.7 Failure to prepare a patient for invasive/blood loss surgery by optimizing hemoglobin, hemodynamics and oxygenation is identified as a patient safety failure and reported to the appropriate committee(s).

- 3.8 In anticipation of invasive procedures, anemia is treated, blood loss is minimized, and multi-modal efforts are undertaken to prevent symptomatic or asymptomatic critical oxygen delivery.
- 3.9 Allogeneic transfusions that are consistent with an institution's transfusion guidelines but were potentially avoidable are reviewed and appropriately addressed.
- 3.10 The hospital transfusion/Patient Blood Management committee must be able to suggest methods of compliance with these standards. Each case presented to the committee must be evaluated with objective criteria.
- 3.11 Proactive PBM and transfusion related content/decision support should be included in the Electronic Health Record system if available.

STANDARD 4: REVIEW AND EVALUATION OF THE PATIENT BLOOD MANAGEMENT PROGRAM

There is a process for evaluating the effectiveness of the patient blood management program. This evaluation is integrated into appropriate quality review activities within each institution. The information is used to improve anemia management, minimize blood loss and improve transfusion practice. This evaluation is based on metrics defined by the hospital. (See related Standards 5 and 11)

GUIDANCE

Comprehensive patient blood management consists of patient-centered strategies to optimize a patient's red cell mass, minimize blood loss and harness the patient's physiologic tolerance of anemia by optimizing oxygenation and hemodynamics. Most importantly, the goal of patient blood management is to improve clinical outcomes. Evaluating the effectiveness of a patient blood management program is an important tool for improving patient outcomes. The effectiveness of a program is determined by measurable improvement in the clinical care of patients. As examples, data collection may include such metrics as the number of units of red cells, platelets, plasma, and cryoprecipitate that are transfused, units transfused per thousand patient days or patient discharge, percentage of inpatients transfused, average pre- and post-transfusion laboratory values and transfusion rates for specific high blood use clinical specialties and patient populations. These metrics should be evaluated in the context of changes in patient outcomes.

Transfusion is associated with significant risks

Human error accounts for the majority of adverse events in transfusion practice

Outgoing education and competency assessment essential to safe transfusion administration

Data collection should not be restricted to transfusion. Other data might include the number of patients enrolled in preoperative anemia management, the use of erythropoietic stimulating agents or intravenous iron, anticoagulant and anti-platelet medication management, use of perioperative cell collection, the use of other pharmacologic agents such as topical hemostatic agents and anti-fibrinolytic drugs, and evaluation of procedural blood loss including phlebotomy compare one hospital's transfusion and patient blood management practices with other similar hospitals.

A hospital may choose to monitor its patient blood management program as part of a multidisciplinary patient blood management committee separate from the traditional transfusion utilization review committee required by accrediting agencies (See Standard 5: Transfusion Guidelines and Peer Review). Alternatively, the transfusion committee may assume the additional functions of a patient blood management committee.

Evaluation of overall transfusion practices by clinical service or section (e.g., Surgery, Orthopedics, etc.), and by individual ordering physician, can provide physicians with an opportunity to see how their transfusion decisions compare to their peers, encouraging improvement in clinical management and in transfusion decisions. Evaluation of specific procedures or diagnostic categories may help facilitate targeted quality improvement initiatives.

Program evaluation and quality improvement is much more than transfusion utilization review and must include systematic evaluation of treatment modalities other than allogeneic transfusion. This evaluation should include a review of access, participation and outcomes related to the use of preoperative anemia management, perioperative autologous blood collection and administration, and inpatient anemia management with erythropoietic stimulating agents and iron. Limited healthcare resources require that strategies to avoid transfusion and manage anemia improve patient outcomes and are cost effective. Evaluation of the patient blood management program should include an analysis of its economic impact on the institution.

INDICATORS

- 4.1 There is a committee that reviews and evaluates all aspects of the patient blood management program. Membership includes but is not restricted to nursing, pharmacy, physician representation of all major medical and surgical services, and administrative leadership.
- 4.2 The ability of the patient blood management program to meet the needs of the patient community is evaluated.

- 4.3 Blood use is monitored by provider, clinical service, case type or procedure as well as hospital-wide. Use of clinical strategies to treat anemia and minimize blood loss is monitored. The data are analyzed to identify potential areas for improvement due to over- or under-utilization.
- 4.4 Blood and blood component transfusions are evaluated using metrics defined by the hospital that allow comparison of blood utilization and transfusion practices with other institutions and the published literature.
- 4.5 Quality measures defined by the hospital are used to assess the clinical efficacy and cost effectiveness of patient blood management clinical strategies in reducing blood utilization, minimizing bleeding and blood loss and managing anemia.
- 4.6 Compliance with patient blood management clinical protocols is monitored to minimize unwarranted variation in practice.
- 4.7 The hospital has a process to assess compliance with blood administration policies and procedures through direct observation by an individual designated as a Transfusion Safety Officer/representative, whenever possible. If direct observation is not possible, there is retrospective evaluation of transfusion records to ensure compliance. The results of direct observation or record review are shared with the committee which can recommend action to address non-compliance.
- 4.8 The hospital defines what constitutes a deviation, significant errors, adverse events and near misses. Inappropriate transfusions and avoidable transfusions, when identified, should be categorized as adverse events even in the absence of a transfusion reaction.
- 4.9 The hospital's patient blood management committee, or transfusion review committee if they are separate, reviews deviations, significant errors, adverse events, near miss events, and sentinel events associated with all aspects of blood ordering and administration including pretransfusion blood specimen acquisition, labeling, and testing as well as the ordering, release, and transfusion of blood and blood components. These should be reported to the hospital Quality Committee and regulatory agencies as required.
- 4.10 The impact of patient blood management and transfusion practice on clinical outcomes such as length of stay, infection rates, ischemic complications and mortality is evaluated.

STANDARD 5: TRANSFUSION GUIDELINES AND PEER REVIEW OF TRANSFUSIONS

There is effective implementation of comprehensive, written guidelines for transfusion of blood products. These guidelines are evidence based. There is peer review of transfusion decisions based on these guidelines. (See related Standards 4 and 11)

GUIDANCE

Effective implementation of comprehensive transfusion guidelines is a key element in a successful patient blood management program. These guidelines establish a standard of care within the organization for clinical transfusion decisions. Ideally, an institution's transfusion guidelines are developed and written by a multidisciplinary group of physicians based on a review of the literature including national or specialty specific

Program effectiveness determined by measurable improvement in patient care

Clinical appropriateness of all transfusion decisions must be reviewed

Use of competing strategies to all allogeneic must be systematically evaluated

physician practice guidelines. They must be evaluated by the hospital's transfusion or quality improvement or quality management committee and approved by the medical staff or medical executive committee or other appropriate authority of the organization's medical staff to ensure that the guidelines are followed.

These guidelines must promote an evidence-based approach to the transfusion of blood components, consistent with the current literature on the risks and benefits of transfusion. The guidelines should be patient centered and include consideration of such factors as patient age,

diagnosis, clinical circumstances, laboratory values such as hemoglobin, hematocrit, platelet count, coagulation testing, and the presence or absence of critical bleeding. Like

all areas in medicine, patient blood management is an evolving discipline. Therefore, the guidelines must be reviewed periodically and revised as new information is published in the medical literature.

Implementation of the guidelines and assurance that the guidelines are being followed may be blood component ordering process should be considered, as this has been shown to be an effective tool supporting adherence to transfusion guidelines. In a paper-based ordering system, this may be accomplished using a check box list of transfusion indications. In a computer based ordering system, choosing the clinical indication for transfusion from a list can be made a required field or order detail. Requiring that the ordering provider indicate the reason for transfusion as part of the ordering process facilitates transfusion utilization review. A computerized provider order entry process is preferred as it provides an opportunity for additional clinical decision support using rules or alerts.

Concurrent or retrospective review of transfusion can provide data to determine if hospital transfusion guidelines are being followed and whether practice is consistent with national guidelines. Prospective review of transfusion requests prior to issuance of blood components offers another opportunity to educate providers and provide clinical consultation. Prospective review of transfusion orders before blood has been dispensed has been shown to be an effective tool to ensure compliance with organization guidelines and should be considered as part of a comprehensive patient blood management program.

Transfusion utilization review is required by accrediting agencies and usually takes place within a multidisciplinary transfusion committee or patient blood management committee. Peer review of transfusion decisions and overall management of patients with bleeding or anemia may also take place as part of clinical service or department quality and clinical case review meetings.

INDICATORS

- 5.1 The hospital has transfusion guidelines that are evidence-based and are approved by the hospital's medical executive committee (MEC) or other appropriate authority of the medical staff.
- 5.2 The transfusion guidelines are readily accessible and available to ordering providers at the time they order transfusions.
- 5.3 The transfusion guidelines take into consideration patient specific factors such as age, diagnosis, laboratory values such as hemoglobin, hematocrit, platelet count, coagulation testing, and presence or absence of critical bleeding and physiologic factors such as oxygenation and hemodynamics.

- 5.4 There is periodic review of the guidelines to ensure that they remain current and relevant, promote an evidence-based approach to the clinical management of the patient, including the transfusion of blood components, and are consistent with the literature and evolving standard of care in transfusion medicine and patient blood management.
- 5.5 There is an effective process for provider-specific peer review of transfusions that uses the guidelines to determine if the transfusion under review was or is medically appropriate, that the transfusion was administered consistent with safe transfusion administration policies and procedures, and that adequate and appropriate documentation is present. Review may be prospective, concurrent or retrospective. If retrospective, it is timely.
- 5.6 Review of transfusion decisions, whether prospective, concurrent, or retrospective, includes recommendations for management without transfusion if it is determined that the transfusion decision was not clinically appropriate or that transfusion was or is avoidable.
- 5.7 The results of transfusion review are communicated to the ordering provider, the chief of the service or department, the medical staff quality improvement or quality management committee and the medical director of the patient blood management program. These results are used for education and are reviewed when a provider's clinical privileges are renewed.

STANDARD 6: PREOPERATIVE ANEMIA EVALUATION AND READINESS FOR SURGERY

There is a process to identify, evaluate and manage preoperative anemia in patients scheduled for elective surgery where the expected amount of surgical blood loss increases the probability of perioperative red blood cell transfusion or where the degree of anemia increases the risk of surgery. (See related Standard 12)

GUIDANCE

Effective blood management requires that transfusion risk be minimized whenever possible. Advanced age, small body size, female gender, chronic renal disease and hepatic or connective tissue disease increases the risk of perioperative transfusion. Modifiable factors that increase the risk of perioperative transfusion includes the use of antithrombotic or antiplatelet pharmacologic agents and pre-existing anemia or iron deficiency, even in the absence of anemia. Preoperative anemia is associated with increased perioperative morbidity and mortality and is the most reliable predictor of significant post-procedure anemia and transfusion requirements. Preoperative anemia is also independently associated with increased perioperative morbidity and mortality.

Optimizing hemoglobin prior to surgery may reduce allogeneic transfusion and decrease postoperative morbidity and mortality. Perioperative transfusion rates may be decreased by identifying elective surgical patients who are anemic, determining the etiology of their anemia, and instituting appropriate therapy that optimizes that patient's hemoglobin and iron stores prior to surgery. Preoperative anemia management begins with screening for anemia followed by laboratory testing to determine its cause. Common causes include iron deficiency, B12 deficiency, chronic kidney disease and anemia of chronic inflammation. Treatment may involve administration of oral or intravenous iron, erythropoietic agents, folate or vitamin B12, and/or referral to a specialist such as a hematologist or gastroenterologist. This surgical readiness or optimization analysis may even require deferral of an elective surgical procedure to a later date if anemia is moderate to severe and the anticipated surgical procedure is truly elective. Consistent and effective preoperative anemia evaluation and treatment usually requires the development of a dedicated outpatient anemia management clinic or incorporation of anemia management as part of a formal pre-surgical evaluation and optimization program.

As part of the preoperative evaluation of patients, anticoagulant and anti-platelet medications should be reviewed to ensure that a plan is in place to modify these therapies in the few days before surgery, if appropriate. Co-morbidities known to be associated with an increased risk of depleted iron stores such as chronic heart failure, chronic renal failure,

rheumatoid arthritis and related diseases and inflammatory bowel disease, or chronic genitourinary blood loss may prompt evaluation of iron stores even in the absence of anemia.

Decreased storage iron may slow recovery from post-operative anemia. A preoperative anemia clinic can be a final opportunity to ensure that a patient is ready for surgery.

INDICATORS

- 6.1 There is a list of elective surgical procedures for which preoperative anemia management screening is required.
- 6.2 Patients who are having a procedure for which preoperative screening is required are identified and assessed at least three to four weeks prior to surgery to allow sufficient time to diagnose and manage anemia, unless the surgery is of an urgent nature and must be performed sooner.
- 6.3 Screening and subsequent laboratory testing is performed to detect anemia and allow diagnosis of the common causes of anemia including iron deficiency anemia, anemia of inflammation (functional iron deficiency), anemia of chronic renal disease, and folate or vitamin B12 deficiency.
- 6.4 A process is in place to ensure that laboratory data have been reviewed. Additional clinical evaluation and laboratory testing is conducted and a referral to a specialist is made as necessary for patients with moderate to severe anemia or anemia of unclear etiology.
- 6.5 Pre-operative evaluation should include review of the patient's medical history, medications including anticoagulant and anti-platelet medications, and co-morbidities, especially those associated with anemia, iron deficiency, or increased risk of bleeding.
- 6.6 Guidelines for treatment of preoperative anemia and iron deficiency without anemia are defined, available and are used to guide care and standardize treatment.
- 6.7 Outpatient treatment with parenteral iron and/or erythropoiesis-stimulating agents occurs when clinically indicated. Timing of treatment is appropriate to the scheduled surgery date.
- 6.8 The results of preoperative anemia screening and the management plan are communicated to the referring surgeon and the primary care physician on a timely basis.

- 6.9 Patients treated for preoperative anemia are followed in the postoperative period to ensure continued management of their anemia during their hospital admission and after discharge.
- 6.10 Elective surgery is deferred and rescheduled in anemic patients when the anemia is reversible if insufficient time is available to correct the anemia before surgery unless the need for surgery is urgent. This decision is the responsibility of the surgeon in consultation with the medical director of the anemia management program.

STANDARD 7: PERIOPERATIVE AUTOLOGOUS BLOOD COLLECTION FOR ADMINISTRATION

The hospital has the ability to collect, process, and reinfuse shed autologous blood. The hospital may also choose to collect blood from patients in the immediate preoperative period (acute normovolemic hemodilution) for reinfusion in the perioperative period.

GUIDANCE

Perioperative blood collection may be performed before surgery, during surgery, and may extend into the postoperative period. Each hospital or organization performing this service is required to have appropriate policies, processes and procedures in place to ensure safe and effective delivery of these services as well as a quality product for recipients.

The goal of perioperative blood collection and reinfusion is to decrease blood loss, preserve

Evidence based guidelines should be established for transfusion of blood products

Transfusion guidelines should be integrated into the hospital's blood and blood component ordering process

Concurrent or retrospective review of transfusion can help evaluate the effectiveness of transfusion guidelines

autologous blood cells and minimize or avoid allogeneic blood transfusion. Collection of whole blood over a period just prior to surgery, typically in the pre-anesthesia area or the operating room itself, with volume replacement as appropriate (acute normovolemic hemodilution or ANH), may also help preserve platelets and plasma clotting factors. In some cases, the autologous product may be separated into different components such as platelet rich plasma, with the intent of creating products that further limit blood loss. Smaller institutions may not have the resources to purchase equipment or provide personnel for perioperative cell recovery and administration. An outside contractor may

be able to provide these services. If perioperative autologous blood recovery is provided through an outside service, the contractor must be in compliance with this standard and all policies and procedures established by that hospital.

Equipment/devices play a large role in the recovery and administration of shed perioperative autologous blood. This equipment should be validated when purchased. Utilization of any equipment critical to this service must conform to national standards of safety and other regulatory requirements. The medical director of the patient blood management program, in addition to any other department-specific directors, must verify and document on a regular basis that operators of this equipment are trained and capable of delivering a safe, high quality product, the qualifications of each operator, initial certification of training, and competency assessment. Perioperative autologous cell recovery for reinfusion is the production of a blood product for transfusion and should be subject to strict process control. The perioperative program must have policies, processes, and procedures identified, reviewed, and approved per hospital policy and consistent with the requirements of all regulatory agencies. Records are maintained, stored, and archived in accordance with record retention policies per the hospital and are concordant with regulatory requirements. Noncompliance or deviations from policies, processes and procedures must be recorded. A mechanism to address any deviations and initiate corrective action, if needed, must be defined. Operators must show continued competence at the time of periodic competency reassessment in order to continue to perform perioperative cell recovery.

ANH is typically conducted by, or under the supervision of, the anesthesia provider before the commencement of surgery. Not all patients are eligible for ANH, and certain comorbid factors limit the efficacy (e.g. baseline anemia) or safety (e.g. pre-load dependent cardiac pathology such as aortic stenosis or hypertrophic cardiomyopathy) of ANH. Patients should be selected carefully based on the procedure, volume of anticipated blood loss, their pre-surgical laboratory values, and comorbid conditions. ANH provides an intraoperative source of fresh autologous whole blood for the patient, thereby establishing a source of red blood cells, platelets and plasma with preserved coagulation factors for subsequent reinfusion. ANH is not without potential risks, including the inability to return a patient's blood if it is collected improperly. The efficacy of ANH is enhanced when combined with other perioperative blood conservation modalities. The utilization of ANH, including the type and number of cases for which it is used, should be monitored by the patient blood management committee.

The impact of autologous blood collection and administration on allogeneic blood transfusion rates should be evaluated by the patient blood management program in cooperation with the transfusion service. This may include periodic analysis of the volume of blood collected and returned, cost savings and expenditures for equipment, maintenance, supplies, and personnel.

INDICATORS

- 7.1 Written policies and procedures address all perioperative autologous blood collection/recovery modalities offered at the hospital. These documents are approved by the chair of anesthesiology and the patient blood management medical director.
- 7.2 Available methods for autologous blood collection/recovery are described in detail.
- 7.3 Indications and contraindications for the use of perioperative autologous blood collection/recovery are described.
- 7.4 There is a list of procedures for which perioperative autologous blood collection/recovery is recommended.
- 7.5 There are written exclusion criteria for patients who are not candidates for acute normovolemic hemodilution.
- 7.6 The hemodynamics of patients undergoing acute normovolemic hemodilution are monitored during collection.
- 7.7 A procedure for reinfusion of collected/recovered autologous blood is defined.
- 7.8 The volume of autologous blood collected/recovered, processed, and reinfused is documented.
- 7.9 Labeling and storage requirements of perioperative autologous blood collections are defined and consistent with local, state and federal requirements. Any deviation is documented, including the rationale for the deviation.
- 7.10 There is a quality assurance program to ensure that perioperative autologous blood collection is indicated, cost-efficient, effective, and safe.
- 7.11 Adverse events including suspected transfusion reactions, complications, and patient safety factors are reported, and are evaluated by the patient blood management medical director. Appropriate action is taken and documented.
- 7.12 Personnel involved in the collection, processing and administration of perioperative autologous blood are qualified on the basis of education and training. Competency is documented and evaluated at least annually.
- 7.13 Equipment and supplies used in the perioperative program are validated before initial use, properly maintained, and revalidated after any major service or repair.
- 7.14 If perioperative autologous blood recovery is carried out as a contracted service from an outside provider, the outside provider is in compliance with this standard.

STANDARD 8: PHLEBOTOMY BLOOD LOSS

There are written guidelines for minimizing blood loss due to phlebotomy for diagnostic laboratory testing.

GUIDANCE

Blood loss secondary to phlebotomy for diagnostic laboratory testing can contribute to patient anemia. Published data suggest that phlebotomy blood loss for a patient may exceed an average of 40 mL per day in critical care units, contributing to a decline in hemoglobin during hospitalization. Blood loss related to diagnostic laboratory testing is a major contributor to anemia in low birth weight neonates. These blood losses place the patient at increased risk for transfusion. Providers should order only those tests that are needed for clinical management. Open ended orders for daily or even more frequent laboratory testing should be discouraged. The need for laboratory testing should be re-evaluated at least on a daily basis.

An aggressive strategy to reduce phlebotomy blood loss must be part of comprehensive patient blood management. Possible elements of a strategy to reduce phlebotomy blood loss could include:

- Educating staff on the need to reduce phlebotomy blood loss.
- Eliminating collection of extra tubes, to be held by the laboratory in anticipation of laboratory testing not yet ordered.
- Increasing the use of point-of-care testing and microsampling, either by use of pediatric tubes, new low volume full size tubes or by using the minimum allowable sample volume in adult tubes.
- Reducing the frequency of mislabeled, hemolyzed, clotted and under- or over-filled tubes that result in repeat sampling.
- Selecting laboratory equipment with low requisite test volume.
- Reducing unnecessary laboratory tests.
- Reducing or eliminating “discard” volume when samples are obtained from indwelling lines, including sterile reinfusion of the “discard” volume when practical.
- Use of closed, needle-free blood sampling systems for arterial and central venous lines to reduce blood waste.
- Use of non-invasive hemoglobin and other laboratory measurements.

INDICATORS

- 8.1 Hospital policies and processes that pertain to phlebotomy for diagnostic laboratory samples address the importance of obtaining only the minimum volume of blood necessary to carry out the ordered laboratory tests and ordering the minimum number of tests needed to manage the patient clinically.
- 8.2 There is a mechanism to identify patients at increased risk for transfusion or who refuse transfusions. Additional measures such as use of microtainers and/or point of care testing and reduction in daily or routine labs orders are considered in order to further minimize blood loss in these patients.
- 8.3 The initial volume of blood withdrawn from an in-dwelling line or catheter, if unsuitable for laboratory testing due to dilution or contamination by medications or intravenous fluids, is returned to the patient whenever possible.
- 8.4 Individuals who reinfuse blood that is unsuitable for laboratory testing are trained and deemed competent according to policy and procedure guidelines. Aseptic technique is used to ensure sterility.
- 8.5 If it is not possible to reinfuse blood unsuitable for laboratory testing, processes are in place to minimize the amount of blood that must be discarded.
- 8.6 The laboratory selects the smallest collection tube size that is practical for the test that is ordered and the instrumentation in the laboratory.
- 8.7 The Patient Blood Management Program in coordination with the laboratory and clinical leadership reviews the frequency of inadequate and mislabeled samples in addition to test ordering patterns and sample requirements to decrease the need to re-sample, reduce unnecessary tests and minimize sample volume.

STANDARD 9: MINIMIZING BLOOD LOSS ASSOCIATED WITH SURGERY, PROCEDURES, COAGULOPATHY OR ANTIPLATELET/ANTITHROMBOTIC MEDICATIONS

There is an ongoing interdepartmental effort involving the patient blood management program, pharmacy, hematology, surgery, anesthesia and transfusion service/ blood bank to minimize blood loss associated with surgery, interventional procedures, and underlying clinical conditions that contribute to impaired hemostasis. Antithrombotic and antiplatelet therapy are appropriately managed in the context of the clinical situation including active reversal where appropriate.

GUIDANCE

Hospital acquired anemia (HAA) is common. When patients are admitted with anemia, their anemia may worsen in hospital. This is due to a combination of factors that include inflammation, iron deficiency, B12 or folate deficiency, and/or an inadequate marrow response to anemia. Acute and subacute blood loss (disease-related or iatrogenic) during hospitalization often plays a major role. Standard 8 addresses the need to minimize iatrogenic blood loss due to phlebotomy. This standard addresses the need to minimize blood loss from all other sources to minimize the severity of HAA and reduce the risk of transfusion. Other factors that affect blood loss and the likelihood of perioperative transfusion include the type of procedure or surgery as well as the skill and experience of the surgeon as well as anticoagulant and anti-platelet medications the patient may be taking at the time of admission. Blood-sparing procedural, surgical and anesthetic techniques should be used whenever possible.

Minimizing blood loss is a multi-disciplinary challenge involving several hospital departments and multiple medical and surgical specialties. Early recognition, diagnosis, and treatment of blood loss are critical to prevent transfusion. Early identification of patients at significant risk for blood loss will help identify patients for whom adjuvant treatments for blood loss prevention are appropriate and cost effective. The identification of patients at significant risk for blood loss should include a review and assessment of any antiplatelet, anticoagulant or antithrombotic agents the patient may be taking. A plan to mitigate the bleeding risk associated with these medications should be part of the effort to minimize blood loss in the hospitalized patient.

The patient blood management program must collaborate with the department of surgery

and anesthesia in developing a culture where the universal goal is to minimize intraoperative blood loss and prevent allogeneic blood transfusion. Developing this culture involves more than considerations of surgical technique. Strategies such as controlled hypotension, normothermia, the availability and use of clotting factor concentrates, topical hemostatic agents, tissue adhesives, technologies to reduce blood loss from the incision itself, and the

Optimizing hemoglobin prior to surgery may reduce allogeneic transfusion

Preoperative anemia management begins with screening for anemia

A preoperative anemia clinic can help ensure that a patient is ready for surgery

use of systemic pharmacologic agents such as antifibrinolytic and prohemostatic agents to reduce blood loss are important considerations. Involving the pharmacy in the selection of these agents is critical.

Effective patient blood management requires an institutional culture in which early intervention for cessation of on-going hemorrhage is prioritized. Aggressive management and definitive intervention, whether surgical, radiologic or endoscopic, should be available when needed. If procedural intervention is clinically indicated for a patient with hemorrhage, this should

be carried out as soon as is medically appropriate within the constraints of the hospital's resources. This may involve medical services other than surgery and anesthesiology, e.g., interventional radiology, endoscopy and others.

Finally, the clinical laboratory plays a vital role in assessing bleeding risk in the surgical patient and defining the etiology of coagulopathic bleeding. Robust diagnostic coagulation testing must be available within a clinically useful timeframe and include a means to assess both quantitative and qualitative platelet or plasma coagulation factor abnormalities. In some cases, near patient or point-of-care coagulation testing may provide the best combination of clinical utility and timeliness. Viscoelastic whole blood coagulation testing such as thromboelastography or rotation thromboelastometry should be considered in the setting of traumatic hemorrhage, organ transplantation, obstetrical hemorrhage and cardiovascular surgery.

INDICATORS

- 9.1 Policies and procedures are defined that minimize intraoperative blood loss and blood loss associated with invasive procedures.
- 9.2 There are guidelines for intraoperative use of pharmacologic agents such as factor concentrates, antifibrinolytic agents, topical sealants and other systemic and topical hemostatic agents and medications to minimize blood loss.
- 9.3 The patient blood management program medical director is actively involved in selection of clotting factor concentrates, topical hemostatic agents, tissue adhesives, and pharmacologic agents, including antifibrinolytic and prohemostatic agents to limit blood loss.
- 9.4 Hospital coagulation testing services have the capability to adequately assess and characterize a patient's hemorrhagic risk factors, assess the level of therapeutic anticoagulation and platelet inhibition and assist in the rapid diagnosis of the likely etiology of coagulopathy in an actively bleeding patient. Results are available in a clinically useful timeframe.
- 9.5 Viscoelastic testing (thromboelastography or thromboelastometry) is available to manage patients with active hemorrhage.
- 9.6 These instruments (e.g. TEG, ROTEM) are in clinical areas that ensure rapid turn-around time from sampling to results.
- 9.7 Connectivity is established to ensure real time screen visibility, so the clinical team can visualize results as clot formation evolves.
- 9.8 There is a competency program with annual competency assessment and initial certification of all new users, under the supervision of the clinical laboratory.
- 9.9 Guidelines encourage early definitive intervention and treatment of acute hemorrhage. Where clinically appropriate, this includes early return to the operating room for correction of a surgical source of bleeding, early referral for interventional radiology and embolization, and early use of endoscopy/colonoscopy and cystoscopy for gastrointestinal hemorrhage or genitourinary hemorrhage.
- 9.10 There should be appropriate referral and consultation protocols in place to assist in the management of patients on anticoagulant and antithrombotic medications or with a history of significant bleeding or coagulation abnormalities.
- 9.11 Guidelines exist for bridging or reversal of therapeutic anticoagulant and antiplatelet therapy that balance bleeding risk against the need for ongoing antithrombotic therapy.

STANDARD 10: MASSIVE HEMORRHAGE PROTOCOL

There is a written protocol for transfusion management of patients with rapid large volume blood loss and hemodynamic instability.

GUIDANCE

Severe hemorrhage may result in hemodynamic instability, hypo-perfusion and anemia related organ injury, leading to the need for large volume transfusion. Definitions for what constitutes massive transfusion vary. A clearly defined operational or dynamic definition

Perioperative autologous blood collection is effective in decreasing blood loss and the use of allogeneic red cells

The clinical efficacy of perioperative autologous blood collection is enhanced when integrated with other patient blood management strategies

Ongoing competency assessment is essential to the safety & quality of recovered red cells

of massive hemorrhage should determine when the massive hemorrhage protocol is initiated. For example, transfusion of greater than 3 units of blood in one hour when ongoing blood loss is anticipated allows the transfusion service to initiate the protocol in consultation with the patient care team. Use of a scoring system to predict on-going hemorrhage in severe trauma may be used to improve the specificity of when the massive hemorrhage protocol should be initiated. The massive hemorrhage protocol should not be restricted to trauma because a variety of elective or emergent surgical procedures as well as vascular, gastrointestinal or obstetrical bleeding may result in the need for large volume transfusion. While transfusion of a large volume of blood

and blood components often result from massive hemorrhage, the focus of a massive hemorrhage protocol should be to stop the bleeding as soon as possible, restore normal

physiologic parameters such as core temperature, blood pH and ionized calcium and restore normal hemostasis. Transfusion therapy is just one part of a massive hemorrhage protocol.

Prompt identification of the patient who may require large volume or massive transfusion is critically important. An early structured response to severe hemorrhage is associated with improved outcomes. Good communication between the transfusion service and the patient care team is essential. Clearly defined responsibilities and authority ensure a coordinated response in a situation that is a true emergency. Patients with severe hemorrhage frequently have an early and profound coagulopathy. Coagulopathy is related to activation of the hemostatic and fibrinolytic system, hypo-perfusion and associated ischemia, and even volume resuscitation. The three factors comprising the lethal triad of acidosis, hypothermia, and coagulopathy must all be corrected in massive transfusion situations, for each one exacerbates the other and contributes to increased mortality. Newer concepts in hemostatic resuscitation advocate for early blood component resuscitation for patients in hemorrhagic shock, limiting the use of crystalloids to minimize dilutional coagulopathy and dilutional thrombocytopenia, and avoiding restoration of normal blood pressure until there is surgical control of hemorrhage.

The first priority in the management of patients with massive blood loss is to stop the hemorrhage. Hospitals must have a protocol to assure hemostatic resuscitation at the same time. Randomized controlled trial data show that early use of tranexamic acid in traumatic hemorrhage reduces blood loss and decreases mortality. Ongoing studies are evaluating the role of tranexamic acid in obstetrical hemorrhage. The protocol should include not only a systematic approach for replacement of red blood cells and other blood components such as plasma, platelets and fibrinogen (either cryoprecipitate or fibrinogen concentrate), but also structured management of hypothermia, hypocalcemia and acidosis. Use of factor concentrates such as prothrombin complex concentrates may be considered in patients with life-threatening bleeding who fail to respond to conventional therapy.

The need for a rapid response to hemorrhage may require that the transfusion service release fixed ratios of red cells, plasma and platelets in the form of massive transfusion packs, especially early in the response. This strategy is now supported by randomized controlled trial data. In addition, readily available laboratory studies or point-of-care tests that evaluate the hemostatic system and physiologic status of patients can be of value in optimizing the treatment of coagulopathy, hypocalcemia, and acidosis and facilitate goal-directed blood component therapy.

The patient population with severe hemorrhage is likely to receive many units of blood and blood components, often released as fixed ratios of red cells, plasma and platelets. A return to goal-directed blood and component therapy once bleeding is controlled is recommended as part of patient blood management. Good patient-centered blood management strategies play a role in minimizing the need for allogeneic transfusion. In particular, periprocedural and peri-operative use of autologous blood collection and reinfusion can help reduce the number of packed red blood cell units needed, reducing the patient's exposure to stored allogeneic blood components and reducing the impact of massive transfusion on the hospital and regional blood supply.

INDICATORS

- 10.1 Criteria are defined for initiating and discontinuing the massive hemorrhage protocol.
- 10.2 In facilities without the capacity to manage patients with massive transfusion needs, there are guidelines for initial damage control resuscitation and rapid transport to another facility.
- 10.3 Responsibility for management of coagulopathy is defined.
- 10.4 Administration of tranexamic acid is considered in all trauma patients with significant hemorrhage.
- 10.5 The massive hemorrhage protocol includes guidelines for management of acidosis, hypocalcemia and hypothermia.
- 10.6 The massive hemorrhage protocol includes guidelines for transfusion of red blood cells, plasma, platelets, cryoprecipitate, and factor concentrates.
- 10.7 Laboratory testing, if available, is used to monitor the patient for acidosis, hypocalcemia, and qualitative and quantitative abnormalities in coagulation.
- 10.8 Laboratory results are available quickly enough to facilitate goal-directed blood component therapy for coagulopathy, anemia and thrombocytopenia.
- 10.9 Where available and clinically appropriate, peri-procedural autologous blood collection and administration is used to minimize the need for allogeneic red cells.
- 10.10 There is a mechanism for multi-disciplinary quality review of complex cases involving massive hemorrhage and transfusion.

STANDARD 11: MANAGEMENT OF ANEMIA IN HOSPITALIZED PATIENTS

There is a process for early identification of hospitalized patients at risk for transfusion due to anemia or at risk for developing anemia during their hospitalization. Anemia is actively managed to reduce the likelihood of transfusion and improve patient outcomes. (See related Standards 4 and 5)

GUIDANCE

An important part of a patient blood management program is to evaluate a patient's risk of transfusion and then take steps to reduce that risk. Many patients admitted to the hospital are anemic at the time of admission as a result of their admission diagnosis or co-morbidity or are at risk to develop anemia while in the hospital due to unavoidable surgical or procedural blood loss, hemodilution, hemolysis, inflammation, iron deficiency, malignancy, other nutritional deficiencies, or a primary hematologic problem.

Recognition, diagnosis, and initial treatment of anemia as early as possible prior to and during an inpatient admission may help avoid the need for transfusion during that hospital admission as well as after discharge or during a future hospital admission. Since even mild anemia is associated with poorer outcomes in a variety of conditions, treatment of anemia without use of allogeneic red cell transfusion may improve patient outcomes even in patients not at immediate risk of transfusion.

The complete blood count, or CBC, establishes the diagnosis of anemia and provides additional information on possible etiologies based on the red blood cell indices and the presence or absence of other hematologic abnormalities. Significant additional information on the probable etiology of the patient's anemia can be obtained from the clinical history and additional laboratory testing easily available with minimal additional blood sampling. Guided by the clinical history and red blood cell indices, this additional testing might include creatinine, reticulocyte count and where available, reticulocyte hemoglobin concentration, iron and iron binding capacity, ferritin, vitamin B12, folate, thyroid stimulating hormone, red cell antibody screening, and direct antiglobulin test.

In some instances, secondary testing may be indicated. Based on the clinical history and the results of initial laboratory tests, additional studies might include additional tests for hemolysis (e.g. direct antiglobulin test, LDH, haptoglobin), serum protein electrophoresis, erythropoietin level, methylmalonic acid, soluble transferrin receptor, or even bone marrow exam. Based on the etiology, treatment should be considered as early as possible prior to or during the hospital admission to optimize the patient's hemoglobin and minimize the likelihood of transfusion.

INDICATORS

- 11.1 Clinical leaders of the patient blood management program have knowledge and experience in the recognition, diagnosis, and management of anemia.
- 11.2 There is a policy requiring that anemia be documented as part of the early clinical assessment of all patients.
- 11.3 Hospital protocols facilitate appropriate diagnosis, evaluation, and management of anemia. Management strategies help minimize the likelihood of transfusion.
- 11.4 Clinical consultation is available to provide recommendations for evaluation and treatment of anemia.
- 11.5 There are guidelines for the use of intravenous iron for treatment of iron deficiency with or without anemia.
- 11.6 There are guidelines for the use of erythropoietic stimulating agents.
- 11.7 Hospital transfusion guidelines recommend against transfusion in asymptomatic, on bleeding patients when the hemoglobin level is greater than or equal to 6.0 - 8.0 gm/dL.
- 11.8 Clinical strategies to optimize hemodynamics and oxygenation are followed before red cell transfusion is considered.
- 11.9 Transfusion of blood and/or components is never used for volume repletion, or to treat anemia that can be treated with specific hematinic medications.
- 11.10 When red cell transfusion is clinically indicated in the non-bleeding patient, only a single unit of red cells is prescribed, followed by clinical reassessment of the patient.
- 11.11 At the time of discharge, there is a plan for post-discharge management of anemia identified or acquired during the hospital admission.
- 11.12 The prevalence of anemia at the time of hospital admission and the incidence of hospital acquired anemia is monitored as a quality indicator.

STANDARD 12: MANAGING ANEMIA IN NON-SURGICAL OUTPATIENTS

There is a program to facilitate identification, diagnosis and management of anemia in nonsurgical patients served by the organization. Anemia is actively managed to improve clinical outcomes and reduce the likelihood of transfusion should the patient require hospitalization.

GUIDANCE

Anemia is extremely common with a prevalence of at least 10-15% in patients over the age of 65. It is estimated that 30-50% of patients with chronic heart failure and more than 50% of patients with late stage renal failure are anemic. Patients with inflammatory bowel disease and autoimmune disorders such as rheumatoid arthritis have a high prevalence of both iron deficiency anemia and anemia of chronic inflammation. Anemia is under-recognized and when recognized, may be under-treated.

Iron deficiency with or without anemia, or anemia as a result of other causes, increases the likelihood that a patient will require a transfusion should they develop an acute illness requiring hospitalization. Anemia contributes to morbidity, has a negative impact on quality of life and

may increase the likelihood of hospitalization in some patients. Anemia at the time of hospital admission increases in-hospital morbidity and mortality. Recent data suggest that treating iron deficiency in chronic heart failure patients improves functional status and may reduce the risk of hospital admission for decompensated heart failure.

Increased red cell production as a result of an erythropoietic response to blood loss or treatment with an erythropoietic stimulating agent (ESA) can result in a functional iron deficiency. A structured program of intravenous iron replacement that ensures such patients are iron replete may reduce the overall cost of managing anemia by allowing a reduction or even elimination in the need for an exogenous ESA.

Latrogenic blood loss for laboratory testing can contribute to anemia

An aggressive strategy to reduce phlebotomy blood loss is vital

Successfully reducing phlebotomy blood losses requires staff education

As the delivery of healthcare migrates away from fee for service and toward reimbursement based on clinical outcomes or is delivered as part of an Accountable Care Organization model, healthcare systems will have a financial incentive to manage anemia across the full spectrum of care. Close coordination with nephrologists who may be managing anemia in the kidney disease patient population and with clinical hematologists who may be managing anemia in patients with or without a malignancy is essential.

INDICATORS

- 12.1 There is an outpatient setting or suitable venue, with input from the patient blood management program medical director that provides evaluation and treatment of anemia in non-surgical patients. This may be incorporated into a preoperative anemia program or made part of another existing program in the organization.
- 12.2 There is a mechanism for notifying the primary care provider that their patient has been treated for anemia while hospitalized and requires follow-up to help ensure completion or continuation of anemia treatment initiated in the hospital.
- 12.3 There is an outreach program to educate the primary care provider community and specialists who care for patients at risk for anemia about the identification, evaluation and management of anemia.
- 12.4 There is a mechanism for providers in the community to refer outpatients to the treatment program for anemia evaluation and treatment.
- 12.5 The program has defined treatment guidelines and protocols for managing iron deficiency anemia, anemia of chronic inflammation and anemia associated with chronic kidney disease. These protocols are evidence-based and reviewed at regular intervals and accepted by the patient blood management or other suitable committee.
- 12.6 The patient blood management medical director works with various clinical specialties such as obstetrics and gynecology, cardiology, rheumatology, gastroenterology and others to identify at-risk patient populations in the community that might benefit from anemia management.
- 12.7 The program is designed to augment the management of anemia by the hematology and oncology service within an organization. Cancer and chemotherapy associated anemia is considered outside the scope of this standard.
- 12.8 Utilization and outcome measures are reported to the patient blood management medical director and program coordinator at least annually and used to evaluate the clinical efficacy and economic impact of the anemia management program.

STANDARD 13: PATIENT BLOOD MANAGEMENT FOR PEDIATRIC PATIENTS

For hospitals that treat pediatric patients, there are age-appropriate evidence-based patient blood management clinical strategies, policies and procedures in place. Patient Blood Management is available to all pediatric patients..

GUIDANCE

This Standard provides guidance for implementing a comprehensive Pediatric Patient Blood Management program. While every hospital may not be equipped to have a dedicated Pediatric Patient Blood Management program, this document highlights important universal clinical strategies that can be implemented to optimize pediatric bleeding management and minimize allogeneic blood product exposure through the use of multi-modal therapeutic strategies that have their central emphasis on the patient rather than the transfusion. Important strategies include treatment of preoperative anemia, standardized transfusion algorithms, the use of restrictive transfusion thresholds, goal-directed therapy based on point of care and viscoelastic testing, antifibrinolytics, and avoidance of hemodilution and hypothermia as supported by evidence.

Management of pediatric bleeding and blood product transfusion presents distinctive considerations. Blood volumes and normal hemoglobin concentrations vary per age and weight, with neonates and infants having higher blood volumes per weight but a lower tolerance to losses. The pediatric patient is more vulnerable to blood loss; for example, a 10 kg infant's blood volume is 80 mL/kg; and a loss of >20% total blood volume (>160 mL) may cause significant hypotension and end organ under perfusion if not managed expeditiously and appropriately. Furthermore, blood losses of small but significant volumes can be under-recognized and under-estimated and therefore mismanaged. Twelve percent of all pediatric cardiac arrests have been attributed to hypovolemia associated with blood loss. Although improvements in hemovigilance have significantly reduced the risk of transfusion-related infections, reports of pediatric non-infectious transfusion-associated complications have increased. Transfusion-related acute lung injury, transfusion-related acute circulatory overload, and hemolytic transfusion reactions are the main culprits with mortality rates as high as 15%30%. Allogeneic red blood cell transfusion is associated with an increased incidence of 30-day mortality and complications in children. In order to decrease the risks associated with transfusion of blood products, a concerted effort must be made by all hospitals and health care workers to avoid unnecessary and inappropriate transfusions as well as over-transfusion. Management of critical pediatric bleeding using massive hemorrhage guidelines complements Massive Transfusion Protocols (MTP); with a focus on managing a patient's critical bleeding in addition to appropriately managing

blood product transfusion. Hospitals caring for pediatric patients should have written Massive Hemorrhage Guidelines incorporating MTP which are based on age and weight readily accessible and available.

These SABM Standards address clinical activities related to pediatric PBM and are intended to optimize clinical outcomes, improve patient safety, and decrease health care costs. The listed indicators provide the reader with a very useful template of required items that must be collectively addressed in the care of the pediatric patient to minimize iatrogenic anemia as well as to limit allogeneic blood component transfusion exposure. These Standards are not intended to provide strict indications, contraindications or other criteria for the practice of clinical medicine and surgery. Clinical decisions should be based on locally accepted practices and on the individual pediatric patient's clinical status.

There is age-appropriate evidence-based PBM clinical strategies, policies, and procedures in place. PBM is available to all pediatric patients.

Neonates, infants, and children are physiologically distinct from adults. Normal blood volume and red cell mass varies by age and weight from birth to adolescence and is different from that of adults. Metabolic rate and baseline oxygen demands may be greater than in adults. However, otherwise healthy pediatric age patients (excluding neonates for which there is a paucity of data) may be more tolerant of severe anemia than critically ill children or those with pre-existing medical conditions with compromised cardiopulmonary function, and may tolerate lower hemoglobin transfusion thresholds, particularly when anemia develops slowly.

Preoperative anemia is prevalent with ~40% incidence in children worldwide and a 15%-20% prevalence in children in industrialized countries; 1% having severe anemia. The main etiology is iron deficiency. The impact of preoperative anemia on postoperative patient outcomes has been reported. Preoperative anemia is independently associated with increasing the risk of requiring a blood transfusion and increasing postoperative morbidity and mortality in surgical and critically ill pediatric patients. Given that preoperative anemia is a significant

Prompt identification of the patient who may require massive transfusion is critically important

Cessation of bleeding is top priority in hemorrhaging patients

Blood conservation strategies can minimize allogeneic transfusion even in severely hemorrhaging patients

health problem and that it has a strong independent association with mortality in neonates, infants and children, outcomes may be improved by timely preoperative screening, diagnosis, prevention and appropriate monitoring and treatment.

Restrictive hemoglobin thresholds have been shown to be indicated and safe in infants, children, and adolescents. Current expert consensus guidelines recommend taking into consideration the individual patient's clinical status along with an optimum hemoglobin target. In general, recommendations for pediatric patients (excluding neonates) suggests that a hemoglobin threshold transfusion target of 7g /dL (70 g/L) is appropriate in a hemodynamically stable well compensated patient and that, in general, a hemoglobin concentration >9g /dL (90 g/L) red blood cell transfusion is unnecessary and inappropriate. Neonates are physiologically quite distinct from infants and young children and require a specific and different set of hemoglobin thresholds and transfusion guidelines. This is confounded by the fact that they have varying hemoglobin levels and types, and potentially a limited inability to tolerate physiologic stress, and a weak immune response. Furthermore, physicians caring for neonates have the challenge of determining and assessing clinical symptoms and physiological markers of critical anemia. Current evidence regarding optimum hemoglobin thresholds in neonates is controversial and evolving. Most evidence-based sources recommend a restrictive hemoglobin threshold in term neonates given that no significant differences in short-term outcomes have been found in comparing a restrictive to a liberal strategy. These guidelines consider the age and the respiratory status (ie, if ventilated or not and the oxygen requirement). Preterm neonates account for the highest transfusion rate and are the most challenging to determine the risk benefit ratio of blood transfusion. Expert opinion favoring a more liberal approach in preterm neonates, suggests that liberal transfusion thresholds may favor improved neurodevelopmental outcomes. Until safety can be concluded by recent ongoing trials (clinicaltrials.gov NCT01702805 and NCT01393496) the indications for red cell transfusion in the premature and low birth weight neonate remain challenging. Specific strategies to optimize peri-partum red cell mass, such as cord clamping, and minimizing phlebotomy to prevent hospital acquired anemia, are important in pre-term neonates. Given that a neonates' total blood volume can often be less than 100 mL (90 mL/kg), blood sampling for diagnostic laboratory testing can quickly lead to significant iatrogenic anemia; and measures should be taken to minimize both sample volume and testing frequency. Initial laboratory testing may be performed on a cord blood sample as one strategy to decrease phlebotomy blood losses. Red blood cell transfusions when indicated should be single donor, leukocyte depleted, irradiated and fresh.

Massive Transfusion Protocols are indicated for patients with imminent or ongoing massive bleeding and, when activated, provide rapid preparation and availability of red cells and plasma components in a 1:1:1 ratio. The goal of MTPs is to avoid coagulopathy as a consequence of platelet and clotting factor depletion secondary to transfusion restricted to red blood cells. While evidence regarding the utility, feasibility, and improvement in patient outcomes when pediatric MTPs are employed is weak and extrapolated from adult MTP's, hospitals should have weight and age-based standardized pediatric MTP's available.

Uniquely challenging settings are those of cardiopulmonary bypass, extracorporeal membrane oxygenation or exchange transfusion; situations analogous to a massive

transfusion. Due to the small blood volume of neonates and infants, multiple blood components are usually indicated. Prematurity and immaturity contribute to sub-optimal coagulation in many patients. Multimodal PBM techniques incorporating massive hemorrhage guidelines, as well as MTP, focus the goal on best managing a patient's critical bleeding and hemostatic derangement in addition to appropriately managing blood transfusion (see Supporting information).

See APPENDIX: Figure 3

Intraoperative cell collection and re-administration (autologous cell salvage) has been limited by the minimum cell volume needed for efficient washing, but smaller bowls and new technologies are extending the use of this strategy to patients with a body weight less than 10 kg. Pharmacologic agents to reduce bleeding and blood loss, such as antifibrinolytics, and to treat anemia, such as iron and erythropoietin, play a similar role in pediatric PBM as they do in adults, but selection and dosing should be based on age and weight and current expert guidelines.

Goal-directed transfusion algorithms using point-of-care technology, such as viscoelastic testing, are helpful to target specific hemostatic derangements and therefore guide transfusion of appropriate products in the appropriate quantities. Strategies should be employed regarding avoidance of hemodilution, hypothermia, hyperkalemia, acidosis, hypotension and maintaining adequate tissue perfusion and oxygenation. Further evidence-based guidelines are needed to determine acceptable thresholds not only for hemoglobin but also for platelets, coagulation factors and fibrinogen to limit unnecessary transfusion of other blood products such as platelets, fresh frozen plasma and cryoprecipitate.

Adolescents can often be managed in a manner very similar to adults. Like adults, patient autonomy about transfusion decisions should be respected and policies in place to address the needs and concerns of pediatric patients who have not reached the age of majority but who refuse transfusion for religious or other reasons. In summary, while there are considerable areas of overlap, pediatric PBM presents a unique set of challenges that should be explicitly addressed in hospitals with or without a formal PBM program, both in dedicated pediatric hospitals and for hospitals that treat both adults and pediatric patients.

While there is less published evidence regarding pediatric PBM strategies and outcomes compared to the adult literature, enough published data are available, along with reasonable extrapolation from the adult literature, to develop a robust PBM program that should decrease the exposure to and risks of transfusion, achieve better patient outcomes while decreasing associated costs.

INDICATORS

- 13.1 There are clearly defined and accepted definitions for neonates, infants, children, and adolescent patients based on age and weight that delineate categories within neonatology and pediatrics for the purposes of patient blood management. Caregivers and hospitals should reach a consensus on these definitions prior to the establishment of specific age and weight related guidelines.
- 13.2 Transfusion guidelines for all blood components should be weight and age appropriate, based on both laboratory and physiologic/clinical criteria, and use restrictive transfusion thresholds for allogeneic red blood cell transfusion when supported by published evidence and expert consensus.
- 13.3 The Transfusion Service has policies and procedures that limit donor exposure in patients who require transfusion, limit the risk of infection, and limit the risk of transfusion associated graft versus host disease.
- 13.4 The Transfusion Service has policies and procedures to ensure fresh or washed packed red blood cells are available and administered to patients weighing less than 10 kg or age <1 year with expected massive transfusion to prevent hyperkalemic cardiac arrest.
- 13.5 Written guidelines for monitoring and managing perioperative bleeding are established, based on evidence and expert consensus and are weight and age appropriate.
- 13.6 Specific measures to reduce blood loss and improve hemoglobin concentration in the pediatric population should be employed when possible. Preoperative screening for anemia is recommended in patients at high risk for blood loss, at least 3–4 weeks prior to surgery, to allow sufficient time to diagnose and manage anemia; unless the surgery is of an urgent nature or must be performed sooner. Specifically pertaining to the neonate, delayed cord clamping and placental blood sampling for initial laboratory studies should be considered at delivery.
- 13.7 Strategies are routinely applied to maintain hemostasis and include b avoiding hemodilution, avoiding hypothermia, avoiding acidosis, preventing and treating metabolic derangements, careful blood pressure control to avoid unplanned hypotension and maintaining adequate tissue perfusion and oxygenation.
- 13.8 Topical hemostatic agents coupled with using meticulous surgical techniques should be considered in neonatal and pediatric surgical patients as an adjuvant to control bleeding.
- 13.9 The use of antifibrinolytics and intraoperative cell salvage collection and re-administration should be considered for all pediatric patients undergoing high blood loss surgery including, but not limited to, cardiac surgery with cardiopulmonary bypass, craniofacial surgery, and scoliosis/orthopedic surgery.
- 13.10 Prothrombin complex concentrates may be considered in neonatal and pediatric

patients undergoing urgent surgery who are receiving vitamin K antagonists.

- 13.11 Policies and procedures are in place and followed that minimize the frequency and volume of blood sampling for diagnostic laboratory testing, facilitate earliest possible removal of sampling lines and provide for the safe return of discard or void volumes.
- 13.12 Non-invasive techniques are used for monitoring of blood gases, hemoglobin and other analytes whenever possible.
- 13.13 Point-of-care test-guided transfusion algorithms for pediatric surgical and critically ill patients are available and used to guide blood component therapy when time permits.
- 13.14 Retrograde autologous priming, miniature circuits, microplegia, ultrafiltration, vacuum assisted venous drainage, and surface modified bypass circuits are for extracorporeal circulation where clinically practical and appropriate.
- 13.15 In pediatric patients, especially those less than 20 kg, blood volume, allowable blood loss and red cell transfusion volume (mL) should be calculated based on weight and the target change in hemoglobin increment.
- 13.16 The decision to transfuse platelets should be based on the platelet count and function, the etiology of the patient's thrombocytopenia and the patient's clinical status. Platelet transfusion volume should be calculated based on weight and desired increase in platelet increment.
- 13.17 The decision to transfuse fresh frozen plasma should be based on laboratory studies, including point of care viscoelastic testing if available, and take into consideration the patient's clinical status and the etiology of the patient's coagulopathy. Fresh frozen plasma transfusion volume should be calculated based on weight and desired improvement in coagulation indices.
- 13.18 The decision to transfuse cryoprecipitate should be based on laboratory studies, including point-of-care viscoelastic testing if available, fibrinogen concentration, the patient's clinical status and the etiology of the patient's coagulopathy. Cryoprecipitate transfusion volume should be calculated based on weight and desired increase in fibrinogen concentration and improvement in coagulations indices. Fibrinogen concentrate may alternatively be considered.
- 13.19 Guidelines are established for the use of erythropoiesis stimulating agents, intravenous and/or oral iron, folate and vitamin B12 in all pediatric patients, including extremely low birth weight and very low birth weight neonates to prevent or mitigate pre-existing or hospital acquired anemia.
- 13.20 Children and adolescents with sickle cell disease should be assessed for stroke risk and transfused with red blood cells, based on current evidence-based guidelines, to prevent stroke.
- 13.21 Pediatric massive hemorrhage guidelines incorporating a massive transfusion protocol based on age/weight should be readily accessible and available.

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<https://www.blood.gov.au/pbm-module-6>

The “Patient Blood Management Guidelines: Module 6 Neonatal and Pediatrics” published by the National Blood Authority, 2016 © was developed by a Clinical/Consumer Reference Group (CRG) representing specialist colleges, organizations and societies in Australia and New Zealand, with the active participation of the clinical community. We have considered their information published as we created Standard 13. Our recommendation: This publication also contains appendix and tables regarding the following areas that may be helpful in developing your Pediatric PBM program:

- Iron requirements in neonates and infants.
- Intravenous Iron delivery calculations.
- Hemoglobin threshold for preterm infants.
- Approximate hgb increments that can be expected following transfusion in neonates.
- Guidance on tranexamic dosing in surgical pediatric patients other than cardiac.
- Pediatric hgb assessment and optimization template.
- Transfusion volume calculation for neonates, infants, and small children.

APPENDIX

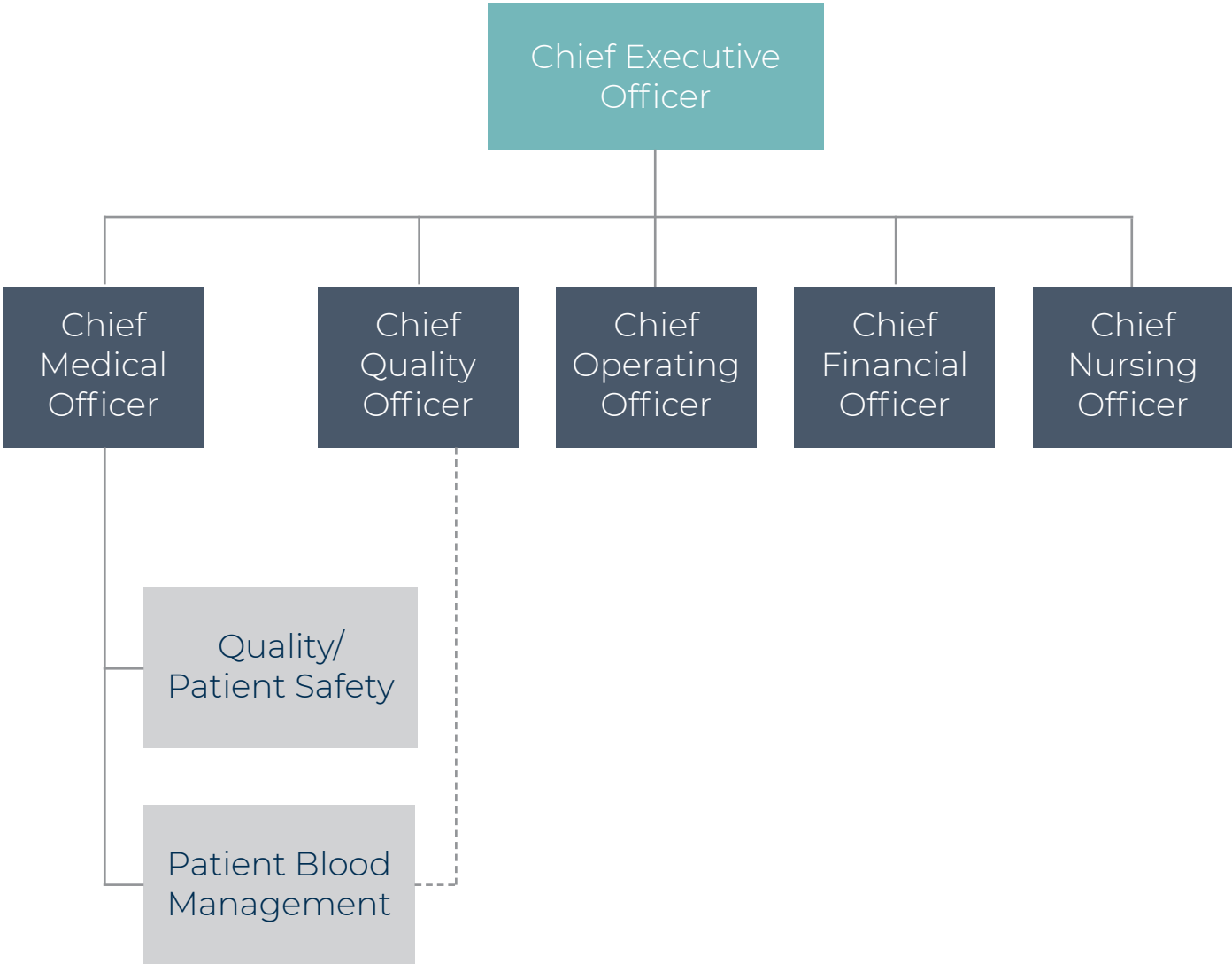


FIGURE 1: Reference 2.3 executive guide

Patient Blood Management Co-Chairs/Directors

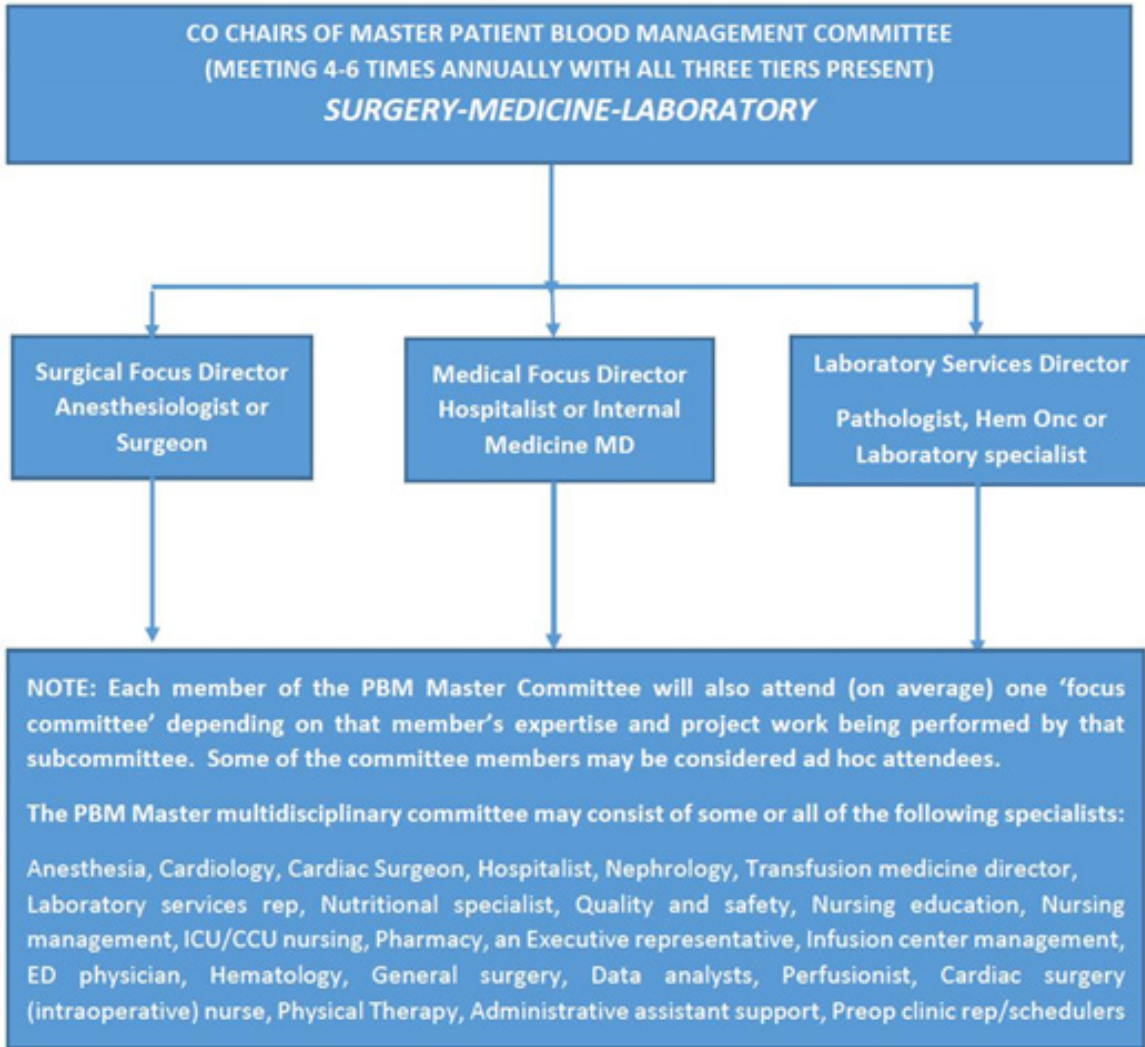


FIGURE 2: Gallagher 2018

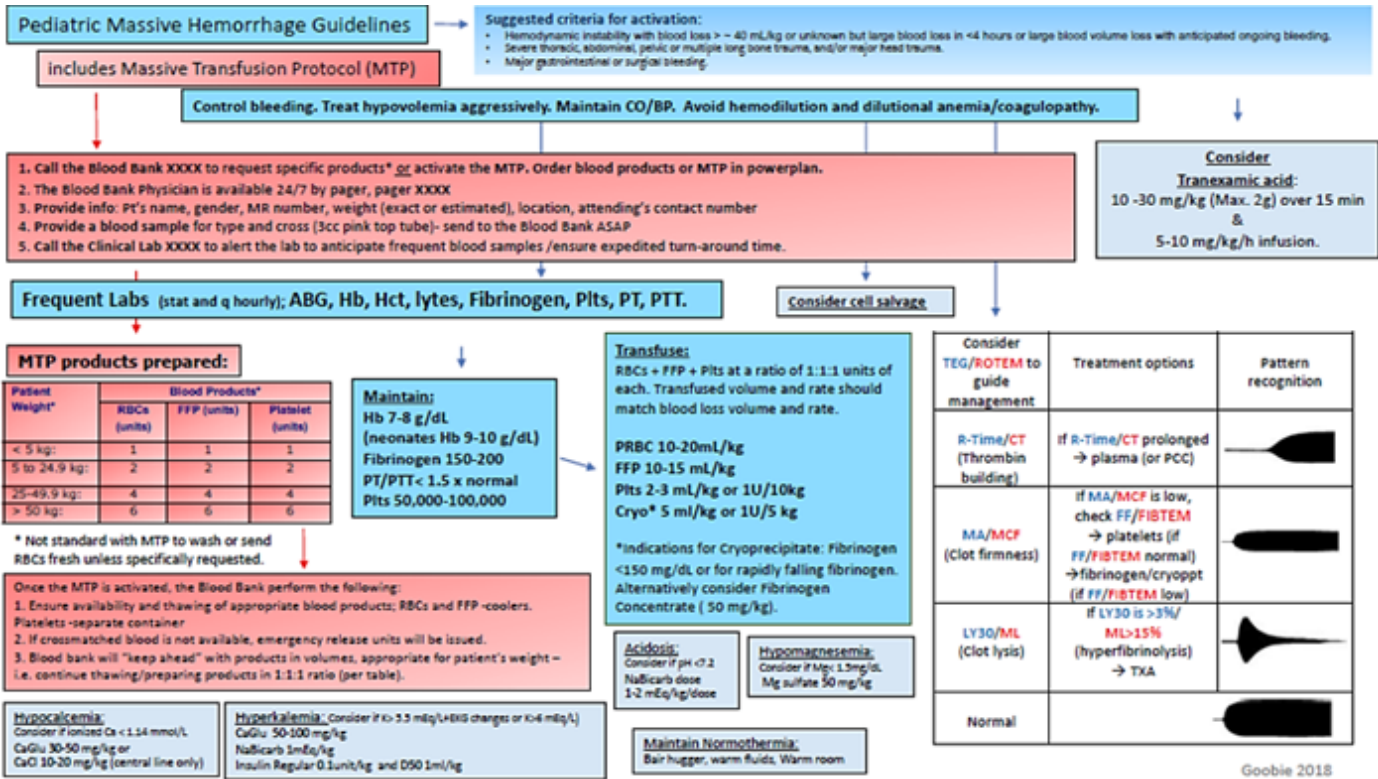


FIGURE 3: S. Goobie et al 2018

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